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## FDA U.S. Food and Drug Administration

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NSSP 2007 Section IV Chapter II. Growing Areas .01 Total Coliform Standards

National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2007

Section IV. Guidance Documents Chapter II. Growing Areas

.01 Total Coliform Standards

## @.02 Bacteriological Standards

Note: The National Shellfish Sanitation Program (NSSP) allows growing areas to be classified using either a total or fecal coliform standard. The NSSP further allows the application of either standard to different water bodies within the state. Once properly classified applying either standard for classification, the NSSP allows the use of the adverse pollution condition or the systematic random sampling strategy for routine classification monitoring as appropriate to the situation in the growing area. For maximum flexibility, a state may wish to adopt the use of both standards and both monitoring strategies as appropriate with each standard. At the Interstate Shellfish Sanitation Conference's annual meeting in 1992, Task Force II recommended that this portion of the *Model Ordinance* be codified according to the standard used and the monitoring strategy employed. The *Model Ordinance* has subsequently been recodified in this manner. This codification represents the delineation of the standards based on total coliforms. The division of the standards based on fecal coliforms is outlined in the main body of the *Model Ordinance* (Chapter IV).

- A. General. Either the total coliform or fecal coliform standard shall be applied to a growing area.
- B. Sampling Stations. The Authority shall ensure that the number and location of sampling stations is adequate to effectively evaluate all pollution inputs into the growing area.
- C. Exceptions.
- (1) Except for growing areas classified as prohibited, in any growing area where there are nonpoint pollution sources which impact the water quality, a minimum of 30 samples, collected under various environmental conditions, shall be required to classify a growing area not previously classified under Chapter IV @ .03.
- (2) Except for growing areas classified as prohibited or when systematic random sampling is applied in growing areas where there are no pollution sources having an effect on the water quality, a minimum of 15 samples shall be required to classify any growing area not previously classified under Chapter IV @ .03 when there are no pollution sources impacting the water quality.
- (3) The Authority is not required to apply the total coliform standard if a detailed study verified by laboratory findings demonstrates that the coliforms recovered from the growing area are not of

direct fecal origin and do not indicate a public health hazard.

- D. Standard for the Approved Growing Area Classification in the Remote Status.
  - (1) Water Quality. The bacteriological quality of every station in the growing area shall meet the total coliform standard below.
  - (2) Total Coliform Standard for the Remote Status. The total coliform geometric mean MPN of the water sample results for each sampling station shall not exceed 70 MPN per 100 ml; and not more than 10% of the samples shall exceed an MPN of:
    - (a) 230 MPN per 100 ml for a 5-tube, decimal dilution test;
    - (b) 330 MPN per 100 ml for a 3-tube, decimal dilution test; or
    - (c) 140 MPN per 100 ml for the 12-tube, single dilution test.
  - (3) Required Sample Collection.
    - (a) A minimum of 2 samples per sampling station shall be collected annually.
    - (b) A minimum of the most recent 15 samples collected per sampling station shall be used to calculate the geometric mean and 10% criteria of the data to determine compliance with the standard established for the approved classification of remote growing areas.
- E. Standard for the Approved Classification of Growing Areas Affected by Point Source Pollution.
  - (1) Water Quality. The bacteriological quality of every station in the growing area shall meet the total coliform standard in  $E \S.(2)$
  - (2) Total Coliform Standard for Adverse Pollution Condition Monitoring. The total coliform geometric mean MPN of the water quality sample results for each sampling station shall not exceed 70 per 100 ml, and, not more than 10% of the samples shall exceed an MPN of:
    - (a) 230 MPN per 100 ml for a 5-tube, decimal dilution test;
    - (b) 330 MPN per 100 ml for a 3-tube, decimal dilution test; or
    - (c) 140 MPN per 100 ml for the 12-tube, single dilution test.
  - (3) Required Sample Collection.
    - (a) A minimum of 5 samples shall be collected annually under adverse pollution conditions from each sample station in the growing area.
    - (b) A minimum of the most recent 15 samples collected under adverse pollution conditions from each sample station shall be used to calculate the geometric mean and 10% criteria of the data to determine compliance with this standard.
    - (c) Sampling station locations shall be adjacent to actual or potential sources of pollution.
- F. Standard for the Approved Classification of Growing Areas Affected by Nonpoint Source Pollution.
  - (1) Exception. If the tidal stage increases the total coliform concentration, the Authority shall use sample results collected during that tidal stage to classify the area.
  - (2) Pollution Sources. Harvest waters shall be:
    - (a) Impacted only by randomly occurring, intermittent environmental events; and,
    - (b) Not impacted by discharges from sewage treatment facilities or combined sewer overflows.
  - (3) Water Quality. The bacteriological quality of every station in the growing area shall meet the total coliform standard in §F (4) or §F (6) as appropriate to the monitoring strategy being used.
  - (4) Total Coliform Standard for Systematic Random Sample Monitoring. The total coliform geometric mean of the water sample results for each sampling station shall not exceed 70 MPN per 100 ml and the estimated 90<sup>th</sup> percentile shall not exceed an MPN of:
    - (a) 230 MPN per 100 ml for a 5-tube, decimal dilution test;
    - (b) 330 MPN per 100 ml for a 3-tube, decimal dilution test.
  - (5) Estimated 90<sup>th</sup> Percentile. The estimated 90<sup>th</sup> percentile shall be calculated by:
    - (a) Determining the geometric mean and logarithmic (base 10) standard deviation for

the sample result from each sampling station; then

- (b) Multiplying the log standard deviation in (a) by 1.28; and
- (c) Adding the product from (b) to the log mean of sample results, and;
- (d) Taking the antilog of the results in (c) to get the estimated 90<sup>th</sup> percentile.
- (e) MPN values that signify the upper or lower range of sensitivity of the MPN test used in the 90<sup>th</sup> percentile calculation shall be increased or decreased by one significant digit.
- (6) Total Coliform Standard for Adverse Pollution Condition Monitoring. The total coliform geometric mean MPN of the water sample results for each sample station shall not exceed 70 MPN per 100 ml and not more than 10% of the samples shall exceed an MPN of:
  - (a) 230 MPN per 100 ml for a 5-tube, decimal dilution test; or
  - (b) 330 MPN per 100 ml for a 3-tube, decimal dilution test; or
  - (c) 140 MPN per 100 ml for a 12-tube, single dilution test.
- (7) Required Sample Collection.
  - (a) Adverse Pollution Condition Monitoring. The Authority shall collect samples at the same frequency as described in §E. 3) for application of the standard under §E. (2).
  - (b) Systematic Random Sample Monitoring. The requirement for systematic random sample monitoring shall be met when:
    - (i) Sample station locations are adequate to produce the data to effectively evaluate all nonpoint sources of pollution;
    - (ii) Sample collection is scheduled sufficiently far in advance to support random collection with respect to environmental conditions. Compliance requires that prior to implementation, the schedule for random sampling shall be documented in the master file for the growing area and adhered to. If conditions at the time of scheduled sample collection are hazardous to the safety of the individuals assigned to collect samples, sample collection shall be rescheduled in accordance with provisions in the sampling schedule;
    - (iii) A minimum of 6 random samples shall be collected annually from each sampling station in the growing area; and
    - (iv) A minimum of the 30 most recent randomly collected samples from each sampling station shall be used to calculate the geometric mean and 90<sup>th</sup> percentile to determine compliance with this standard.
  - (c) Transition from Adverse Pollution Condition Monitoring to Systematic Random Sample Monitoring. If the Authority:
    - (i) Does not have 30 recent randomly collected sample results from each station, then the previous 15 samples collected under adverse pollution conditions may be used with the most recent random samples to meet the minimum 30 sample requirements for a transition period not to exceed 3 years; and
    - (ii) Uses the transition period described in (i), as additional random samples are collected, the random samples shall chronologically replace the samples collected under adverse pollution conditions (e.g. sample 31 replaces sample 1)
- G. Standard for the Restricted Classification of Growing Areas Affected by Point Source Pollution and Used as a Shellfish Source for Shellfish Depuration.
  - (1)-Water Quality. The bacteriological quality of every sample station in the growing area shall meet the total coliform standard in §G. (2).
  - (2) Total Coliform Standard for Adverse Pollution Condition Monitoring. The total coliform geometric mean MPN of the water sample results for each station shall not exceed 700 per 100 ml and not more than 10% of the samples shall exceed an MPN of:
    - (a) 2,300 MPN per 100 ml for a 5-tube, decimal dilution test; or

- (b) 3,300 MPN per 100 ml for a 3-tube, decimal dilution test; or
- (c) 1,386 MPN per 100 ml for a 12-tube, single dilution test.
- (3) Required Sample Collection. Samples shall be collected in accordance with §E. (3).
- H. Standard for the Restricted Classification of Growing Areas Affected by Nonpoint Source Pollution and Used as a Shellfish Source for Shellfish Depuration.
  - (1) Exception. If the tidal stage increases the total coliform concentration, the Authority shall use samples collected under that tidal stage to classify the area.
  - (2) Pollution Sources. Growing areas shall meet the requirements in §F. (2).
  - (3) Water Quality. The bacteriological quality of every sample station in the growing area shall meet the total coliform standard in §H. (4) or §H. (6) as appropriate to the monitoring strategy being used.
  - (4) Total Coliform Standard for Systematic Random Sample Monitoring. The total coliform geometric mean MPN of the water sample results for each sample shall not exceed 700 per 100 ml and the estimated 90<sup>th</sup> percentile shall not exceed:
    - (a) 2,300 MPN per 100 ml for a 5-tube, decimal dilution test; or
    - (b) 3,300 MPN per 100 ml for a 3-tube, decimal dilution test.
  - (5) Estimated 90<sup>th</sup> percentile. The estimated 90<sup>th</sup> percentile shall be calculated by the same method described in §F. (5).
  - (6) Total Coliform Standard for Adverse Pollution Condition Monitoring. The total coliform geometric mean MPN of the water sample results for each station shall not exceed 700 MPN per 100 ml and not more than 10% of the samples shall exceed an MPN of:
    - (a) 2,300 MPN per 100 ml for a 5-tube, decimal dilution test; or
    - (b) 3,300 MPN per 100 ml for a 3-tube, decimal dilution test; or
    - (c) 1,386 MPN per 100 ml for a 12-tube, single dilution test.
  - (7) Required Sample Collection.
    - (a) Adverse Pollution Condition Monitoring. The Authority shall collect samples at the same frequency as described in §E. (3), for application of the standard under §H. (6).
    - (b) Systematic Random Sample Monitoring. The Authority shall collect samples in the same manner and at the same frequency as specified in §F. (7)(b) for application of the standard under §H. (4).

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